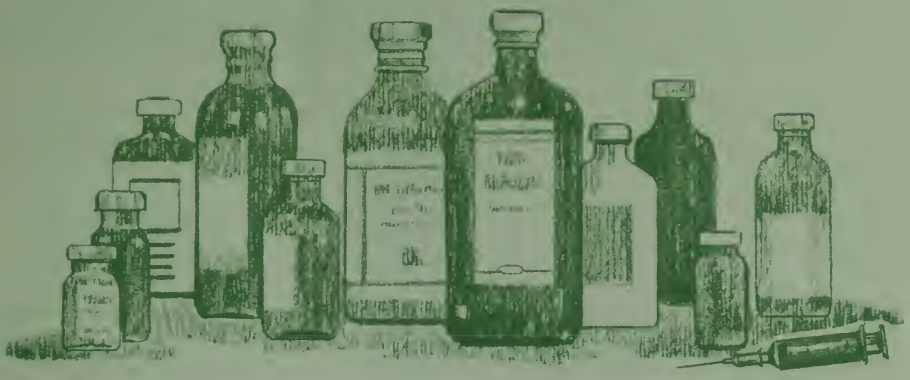
care and use of veterinary biologics

VETERINARIAN'S CHECK LIST

U.S. Department of Agriculture • Program Aid No. 841

Veterinarians select biologics from an array of some 260 different kinds of U.S. licensed products and use them to diagnose, prevent, or treat 58 animal diseases.



Most veterinary biologics do the job for which they were intended. Some fail because they are mishandled or incorrectly administered. Even a small percentage of failures is too costly to tolerate because of the importance of disease control to efficient animal agriculture and the widespread use of biologics. For example, a 1 percent failure rate for the 6 to 8 billion doses of vaccines administered each year would leave thousands of animals unprotected against disease.

Use of veterinary biologics has increased nearly 3,000 percent during the past 2 decades. Vaccines have led in this expanded use and now account for more than 90 percent of the veterinary biologics produced in the United States.

For more than a half-century, the U.S. Department of Agriculture has regulated the interstate marketing of veterinary biologics to help assure that animal vaccines, serums, antitoxins, and other biologics are the best that science can provide to protect our $21 billion livestock and poultry industries. The biologics industry has responded to regulations and to needs of farmers and ranchers by developing and improving biologics that meet increasingly higher standards.

In the process of licensing and regulating manufacturers of veterinary biologics, USDA inspects production plants, designates industry testing procedures, oversees labeling of products, and subjects biologics to various tests for sterility, safety, and potency. These measures and the safeguards employed by industry help assure that only safe and effective biologics reach the market.

users share RESPONSIBILITIES

USDA's regulatory authority does not extend to handlers and users of veterinary biologics. The task of keeping a product safe and effective after it leaves the production plant lies ultimately with the handler and the veterinarian who administers the biologic. How diligently this task is carried out bears importantly on the protection of animals, the integrity of the biologic, and professional reputation of the veterinarian.

mishandled biologics may be DANGEROUS

Improper handling during marketing, storage, and use can rapidly degrade biologics and make them inert, or convert them from beneficial disease fighters to dangerous disease spreaders. Subtle changes may cause them to lose potency; contamination may make them dangerous.

An ineffective vaccine poses a double-barreled problem: You can't look at the vaccine and detect deterioration with any degree of certainty; and you can't look at an animal vaccinated with the product and detect failure to develop immune response. Unfortunately, the first signs of failure may be an unexpected and costly outbreak of the disease that vaccination was supposed to prevent.

Failure of vaccine users to follow manufacturers' directions is one of the most frequent causes of ineffective vaccination.

veterinary biologics . . . checklist

Care and Handling

- ☑ MAKE it your business to know how your biologics are handled from the manufacturer's plant until you receive them.
- ☑ MAKE CERTAIN the shipper packs biologics so they remain cool during shipment.
- ☑ DON'T stockpile biologics . . . buy just enough to meet your immediate needs.
- ☑ CHECK labels and literature for special requirements that may be necessary for storage and handling.
- ☑ STORE biologics in subdued light at a temperature of 35° to 45° F.
- ☑ PACK biologics in ice during actual use in the field.

Administering

- ☑ READ all directions and precautions on container labels and in accompanying literature.
- ☑ RESTORE only enough desiccated biologic for immediate needs. Destroy unused portions.
- ☑ VIGOROUSLY SHAKE bacterial suspensions to assure an even mixture.
- ☑ DON'T MIX various finished products.
- ☑ STERILIZE all instruments and vaccinating equipment that contact biologic . . . avoid chemical sterilization when using living vaccines.
- ☑ USE only the route of administration indicated in directions.
- ☑ CAREFULLY CLEANSE and disinfect site of inoculation.
- ☑ ADMINISTER the recommended full dose.

Post Administration

- ☑ BE ALERT for anaphylactoid shock . . . have proper drug ready to counter reaction.
- ☑ KEEP complete records of biologics serial numbers, expiration dates, type of product administered to each animal.
- ☑ DON'T save unused portions of biologics . . . they can easily become contaminated.
- ☑ DESTROY empty biologic containers by burning or burying at least 18 inches deep in level ground.
- ☑ IMMEDIATELY REPORT any adverse reactions to biologics to the USDA Veterinary Biologics Division.
- ☑ KNOW requirements for withholding slaughter animals from market following vaccination; inform your clients.

Some common errors in vaccination procedure that have led to hog cholera outbreaks were: Omitting serum when it was called for, administering an inadequate amount of serum, commingling vaccinated with nonvaccinated animals, vaccinating animals under stress, vaccinating pregnant or nursing sows, and using the wrong biologic.

labels and literature are GUIDELINES

Guidelines for use of U.S. licensed biologics are carefully spelled out on container labels and in accompanying literature. Manufacturers submit all biologic labels and literature for review and approval by USDA's Veterinary Biologics Division. Labels must show the true name of the product, serial number, name and address of manufacturer, a dosage table, quantity, storage instructions, precautions, and expiration date.

By following the basic guidelines provided for handling, care, and use of biologics, veterinarians can keep the products they use at maximum potency and maintain their safety and effectiveness. The very nature of biologics . . . the fact they are made from living disease organisms or their products . . . signals the need for care. Although striking advances have been made with biologics, proven procedures need to be followed for shipping, storage, and administration.

report adverse reactions IMMEDIATELY

Report abnormal adverse reactions to vaccination as soon as possible to the veterinarian in charge of USDA's Animal Health Division located in your State or direct to the Veterinary Biologics Division. Complaints involving a vaccine are investigated by members of USDA's Veterinary Biologics Division.

Provide information about the vaccination procedure used and all other circumstances that may aid in determining the cause for the reaction. Describe the reaction in detail, and include results of postmortem examinations and any laboratory tests conducted. Report serial numbers of biologics used, the name of the manufacturer, date of administration, kind and condition of animals vaccinated, and the livestock owner's name and address. Reports made direct to the Veterinary Biologics Division should be addressed as follows:

Veterinary Biologics Division
Agricultural Research Service
U.S. Department of Agriculture
Federal Center Building
Hyattsville, Maryland 20782

how USDA helps assure safe, effective BIOLOGICS

All veterinary biologics marketed across State lines are produced under a United States Department of Agriculture Veterinary License. These products have U.S. Veterinary License numbers on the label.

A USDA license is granted for a biologic only after it has met all requirements for purity, safety, and potency and it is determined that the biologic will serve the intended purpose. USDA requirements are precise. They include an assessment of the manufacturer's laboratory facilities and equipment, and professional personnel. The manufacturer provides USDA with plans for production, testing procedures, information, and research data on new products; proposed trade labels and literature, cultures of organisms used, and samples of the finished product. All of this information and material is carefully examined and analyzed by highly trained USDA specialists.

Extensive field tests may be conducted by the firm under the supervision of the Veterinary Biologics Division if the product employs a new concept for immunization. Manufacturer's tests of the product for sterility, purity, safety, and potency must meet USDA standards before the biologic is released for production.

USDA continues careful appraisal of biologics after they have been licensed for use. Veterinary Biologics Division inspectors periodically inspect manufacturing plants, check production and testing techniques, and collect samples of biologics for testing.

The national program of surveillance over veterinary biologics started in 1913, under authority of the Virus-Serum-Toxin Act. Specifically, the Act provides the Secretary of Agriculture with authority to regulate production and marketing of veterinary biologics placed in interstate and international commerce. Regulatory activities are conducted by the Veterinary Biologics Division, a part of USDA's Agricultural Research Service.

LOOK FOR THE U.S. VETERINARY LICENSE NUMBER ON THE LABEL

- Purchase wisely
- Handle carefully
- Store properly
- Administer skillfully

Veterinary Biologics Division
Agricultural Research Service
U.S. Department of Agriculture

Washington, D. C.

Issued June 1968

U. S. GOVERNMENT PRINTING OFFICE : 1968 O - 298-949